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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,685	10/11/2005	Yukako Fukuhira	Q90825	3807
23373 7590 02/02/2010 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037				
EXAMINER HELM, CARALYNNE E				
ART UNIT		PAPER NUMBER		
1615				
NOTIFICATION DATE		DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/552,685

Applicant(s)

FUKUHIRA ET AL.

Examiner

CARALYNNE HELM

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2009 and 04 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 1-3 and 13-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 12/1/09
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

To summarize the current election, applicants elected group II without traverse.

Claim 1-3 and 13-18 were withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Terminal Disclaimer

The terminal disclaimer filed on November 4, 2009 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on US Application No. 10/580029 has been reviewed and is accepted. The terminal disclaimer has been recorded.

MAINTAINED REJECTIONS

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The four factual inquiries of *Graham v. John Deere Co.* have been fully considered and analyzed in the rejections that follow.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4-9 and 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimomura et al. (JP-2001-157574 – see IDS and attached translation) in view of Johnsson et al. (Biophysical Journal 2001 80:313-323), Nishikawa et al. (Materials Research Society Symposium Proceedings 2002 724:N11.7.1-N11.7.6), and Maruyama et al. (Thin Solid Films 1998 327-329:854-856).

Maruyama et al., Nishikawa et al. and Shimomura et al. teach a honeycomb structured film comprised of biodegradable polymer and an amphiphilic compound/polymer that acts as a surfactant (see Maruyama et al. page 855 column 1 paragraph 1, Nishikawa et al. N11.7.3 paragraph 1, and Shimomura et al. paragraph 9; instant claim 4). Nishikawa et al. teaches polylactic acid and polycaprolactone as biodegradable polymers used in the film (see Nishikawa et al. N11.7.3 paragraphs 1 and 2; instant claims 5-6 and 8). Shimomura goes on to teach a larger set of biodegradable polymers that are suitable for use in the invention that include polycarbonates, polyethylene adipate, polyhydroxybutyric acid, polyethylene carbonate, and polybutylene carbonate (see paragraph 10; instant claims 5-8). Further the proportion of biodegradable polymer to amphiphilic compound/polymer is taught to be 10/1 by Nishikawa et al. and between 1/1 and 50/1 by Shimomura et al. (see Nishikawa et al. page N11.7.1 paragraph 3 and Shimomura et al. paragraph 9; instant claim 12). The three references do not teach phospholipids in particular as the amphiphilic compound.

Johnsson et al. teach that the phospholipid dioleoylphosphatidylethanolamine (L- α -phosphatidyl ethanolamine dioleoyl) forms an inverted hexagonal structure (honeycomb) in aqueous solution (see page 313 column 1 paragraph 1; instant claims 4, 9, and 11). Maruyama et al. teach that self-assembling molecules that form three-dimensional nanoscale structures are combined with polymers to form microscale features in structured films (e.g. honeycomb structures). L- α -phosphatidyl ethanolamine dioleoyl is an amphiphilic compound that would qualify as one such self-assembling

molecule, is biodegradable itself, and as a phospholipid, has surfactant properties. It would therefore have been within the technical grasp of one of ordinary skill in the art at the time of the invention to utilize L- α -phosphatidyl ethanolamine dioleoyl in the invention of Maruyama et al., Shimomura et al., and Nishikawa et al. Thus claims 4-9 and 11-12 are obvious over Maruyama et al., Shimomura et al., Nishikawa et al., and Johnsson et al.

Claims 4 and 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimomura et al. in view of Huang et al. (U.S. Patent No. 5,283,122), Nishikawa et al., and Maruyama et al.

Maruyama et al. and Nishikawa et al. teach a honeycomb structured film comprised of biodegradable polymer and an amphiphilic compound/polymer that acts as a surfactant (see Maruyama et al. page 855 column 1 paragraph 1, Nishikawa et al. N11.7.3 paragraph 1, and Shimomura et al. paragraph 9; instant claim 4). Nishikawa et al. teaches polylactic acid and polycaprolactone as biodegradable polymers used in the film (see Nishikawa et al. N11.7.3 paragraphs 1 and 2; instant claim 4). The two references do not teach phospholipids in particular as the amphiphilic compound.

Huang et al. teach that the phospholipid phosphatidyl ethanolamine (L- α -phosphatidyl ethanolamine) forms an inverted hexagonal structure (honeycomb) in aqueous solution (see claims 15 and 16; instant claims 4 and 9-10). Maruyama et al. teach that self-assembling molecules that form three-dimensional nanoscale structures are combined with polymers to form microscale features in structured films (e.g.

honeycomb structures). L- α -phosphatidyl ethanolamine is an amphiphilic compound that would qualify as one such self-assembling molecule, is biodegradable itself, and as a phospholipid, has surfactant properties. It would therefore have been within the technical grasp of one of ordinary skill in the art at the time of the invention to utilize L- α -phosphatidyl ethanolamine in the invention of Maruyama et al., Shimomura et al., and Nishikawa et al. Thus claims 4 and 9-10 are obvious over Maruyama et al., Nishikawa et al., and Huang et al.

Response to Arguments

Applicants' arguments, filed January 21, 2009 and November 4, 2009, have been fully considered but they are not deemed to be persuasive.

Applicants argue that the instant invention can only be formed using hydrophobic organic solvents. While applicants may intend for their honeycomb structure to originate from an organic solvent, this is not a requirement in the claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Moreover, even if such a process were recited as part of the product recitation, there is nothing of record to demonstrate any structural difference between a honeycomb film made from applicants' intended methodology and one that would result from the combined references as cited. Both claimed phosphatidyl ethanolamine compounds were known to generate honeycomb structures in aqueous solution and to be self-assembling molecules, as taught necessary for the honeycomb film structure of

Maruyama et al., Shimomura et al., and Nishikawa et al. Thus, there is no reason for one of ordinary skill in the art to believe that a honeycomb film could not be generated based upon the teachings of the cited prior art references.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The rejections and/or objections detailed above are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Friday 9-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
Examiner, Art Unit 1615

/Robert A. Wax/
Supervisory Patent Examiner, Art Unit 1615